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Daisha L. Seyfer, MD¹, Don C. Van Dyke, MD¹,
David P. Wacker, PhD¹, Stacy A. McConkey, MD¹,
Linda Cooper-Brown, PhD¹, Melanie H. Bachmeyer, MS¹,
and Clarence D. Kreiter, PhD¹

Abstract

In recent decades, national and international surveys have reported increased usage of psychotropic medications in children. A review of the computerized clinic records for 709 children seen in a behavioral specialty clinic from January 2001 to December 2007, inclusive, in a rural US state was completed. The number of children diagnosed with disruptive behavior disorder/behavior management issues increased over the 7-year period, but this was balanced by an increased number of referrals. The number of children referred over the 7-year period increased from 77 in 2001 to 127 in 2006, a 39% increase. The overall percentage of children on medications at time of first visit showed some variability, but it did not increase over the years 2001 to 2007. The results of this study suggest that the previously reported increase in psychotropic medication usage in pediatric patients is not consistent across all diagnostic categories or in all regions of the United States.

Keywords

disruptive behavior disorder, behavior problems, pediatric medication use, psychotropic medication

Introduction

Some studies over the past several years have reported a significant increase in the use of psychotropic medications in young children.¹⁻⁴ In particular, there has been much concern about increasing usage of antipsychotic medications in children. Although there have been several randomized controlled trials to evaluate the use of these medications in children, there is still much to discover in terms of safety, therapeutic value, and long-term effects. Some of these medications, particularly antipsychotics, are known to have multiple side effects in some populations of adults. Therefore, it is understandable that the increased prevalence of these medications in children is of concern to parents and health care providers alike.

The purpose of this study was to determine if a pattern of increased psychotropic medication usage was observed in children with behavior disorders presenting to a behavioral pediatrics clinic in a rural Midwest state. This study

was conducted to evaluate patterns of medication usage from January 2001 to December 2007. This study differs from many of the previously published studies in that we studied the use of psychotropic medications in a specific population (children with behavior disorders) rather than the pediatric population at large.

Methods

This study was approved by the Institutional Review Board of the University of Iowa Carver College of Medicine.

¹University of Iowa Hospitals and Clinics, Iowa City, IA, USA

Corresponding Author:

Daisha L. Seyfer, Division of Behavioral Health, Nationwide Children's Hospital, 700 Children's Drive, Columbus, OH 43205, USA
Email: daisha.seyfer@nationwidechildrens.org

Table 1. Children with DBD/BMI using psychotropic medications

Year	N1	N2, n (%)	Male/Female	Stimulant, n (%)	Antidepressant, n (%)	Antipsychotic, n (%)	Adrenergic, n (%)	Anticonvulsant, n (%)	Other, n (%)
2001	77	10 (13)	52/25	9 (11.7)	3 (3.9)	0	4 (5.2)	0	0
2002	88	18 (20.5)	68/20	14 (15.9)	1 (1.1)	1 (1.1)	4 (4.5)	2 (2.3)	2 (2.3)
2003	83	12 (14.5)	62/21	9 (10.8)	1 (1.2)	3 (3.6)	2 (2.4)	0	2 (2.4)
2004	95	15 (15.8)	60/35	10 (10.5)	1 (1.1)	3 (3.2)	5 (5.3)	0	1 (1.1)
2005	124	14 (11.3)	88/36	9 (7.3)	1 (<1)	3 (2.4)	2 (1.6)	0	1 (<1)
2006	127	28 (22.0)	90/37	18 (14.0)	2 (2.0)	6 (5.0)	5 (3.9)	1 (<1)	3 (2.3)
2007	115	12 (10.4)	87/28	6 (5.2)	0	1 (0.9)	4 (3.5)	0	2 (1.7)

N1 = Number of children diagnosed with Disruptive Behavior Disorder or equivalent

N2 = Number of children entering the clinic taking psychotropic medication(s)

Patient Population

The Behavioral Pediatrics Clinic (BPC) is a pediatric specialty clinic that serves children 10 years of age or younger who are of typical development and display severe behavior problems at home and/or school. This clinic uses a multidisciplinary approach to address pediatric behavior issues. Medications are prescribed, if needed, as part of a multi-faceted approach to behavior modalities and modification. Referrals to the clinic occur primarily from the families' pediatrician or other primary health-care provider, with the most common reasons for referral being noncompliant and aggressive behaviors (approximately 80% of referrals). Outpatient evaluations were conducted once per week, and each evaluation was conducted over a 4-hour period. The interdisciplinary team included a behavioral pediatrician, pediatric nurse practitioner, social worker, speech/language pathologist, and behavioral psychologist.

Design Method

The study was completed in 2 steps. A review of appointment books as well as the computerized clinic record for children seen in the BPC from January 2001 to December 2007 was completed. Children meeting the study criteria were identified, and demographic data, clinical data, and current medication use were recorded and analyzed. This analysis was then compared with other reports in the biomedical literature.

The cohort inclusion criterion was receiving one or more of the following diagnoses in clinic at the time of the first appointment: disruptive behavior disorder (DBD), behavior management issues/problems/concerns (BMI), or disruptive behavior (DB). This diagnostic category is for disorders characterized by conduct or oppositional defiant behaviors that do not meet the criteria for conduct disorder (CD) or oppositional defiant disorder (ODD). Children with diagnoses of autism spectrum disorder or any degree of intellectual disability (as identified in the

medical record) were excluded from the study population. It was thought that children in those populations may have an increased incidence of psychotropic medication usage and may skew the study results. Thus, we were interested in studying only those children with behavior disorders who were thought to be of typical development (defined as no identified developmental delays).

A detailed medical record search was conducted of computerized medical records of the study children. Current medications were defined as those taken at the time of the initial visit, or within the most recent 48 hours. Psychotropic medications used in this study included stimulants, antipsychotics, α -adrenergic agonists, antidepressants, anticonvulsant mood stabilizers, and other medications prescribed explicitly for the purpose of modifying behavior/s (such as diphenhydramine given to children at bedtime for the purpose of inducing sleepiness). All records were reviewed by one author (DS). A second rater (MB) independently reviewed the records for each year. She reviewed 25% of participants identified for inclusion by the primary rater.

Results

The summary of the data collected from the computerized medical chart review appear in Table 1. The number of children referred over the 7-year period increased from 77 in 2001 to 127 in 2006, a 39% increase (Table 1). Figure 1 demonstrates that the increasing number of children diagnosed with DBD/BMI was mirrored by an increased number of referrals. This nonsignificant trend for the proportion of children on medications actually decreased slightly as the years progressed.

While the number of children on medications at time of first visit also increased over the 7-year period, this was mirrored by an increased number of behavioral diagnoses (Figure 1). The overall percentage of children taking medications at time of first visit did show some variability, but it did not increase over the years 2001-2007 (Figure 1).

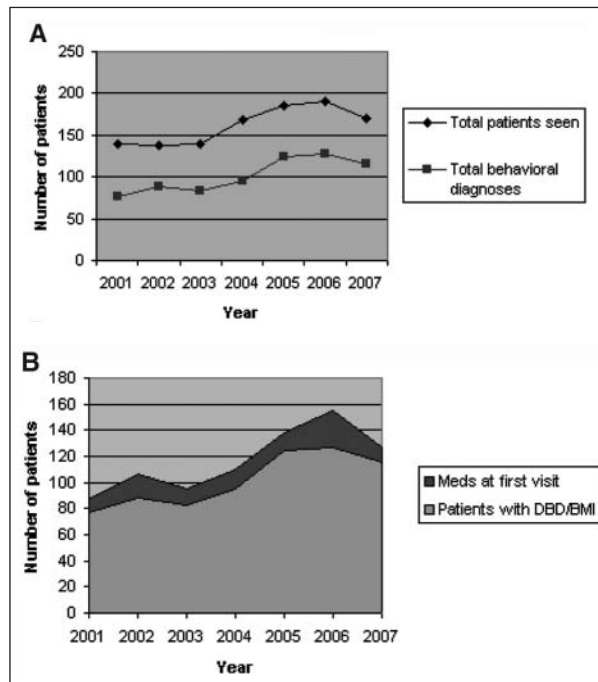


Figure 1. (A) Total patients seen versus patients with behavioral diagnoses and (B) patients with behavioral diagnoses on medications at time of first visit
Abbreviation: DBD, disruptive behavior disorder; BMI, behavior management issues/problems/concerns.

Statistical Analysis

Interrater agreement of the cases identified as meeting the study criterion was 97.74%. Interrater agreement on those cases was also compared for age, gender, and psychotropic medication usage. An agreement of medication usage was defined as the raters reporting the exact same assortment of medications. Interrater agreement for age, gender, and medication usage were 99.44%, 99.44%, and 98.87%, respectively.

The standard deviation for the percentage of children taking medication was calculated for each year of study. The results, appearing in Figure 2, do not show a statistically significant difference between any 2 years ($P > .05$ for all comparisons). In addition, the proportion for the first 4 years was similar to the proportion for the last 3 years ($P = .158$ and $P = .144$, respectively), and a χ^2 analysis demonstrated that the 2 groups were not statistically different ($\chi^2 = 0.1357$, $P = .7126$). A power analysis of our ability to detect a difference showed that for subjects monitored for the first 4 years (group 1, $N = 343$) versus those monitored for the last 3 years (group 2, $N = 366$), the study had adequate power to detect differences as small as 0.10 with 90% power.

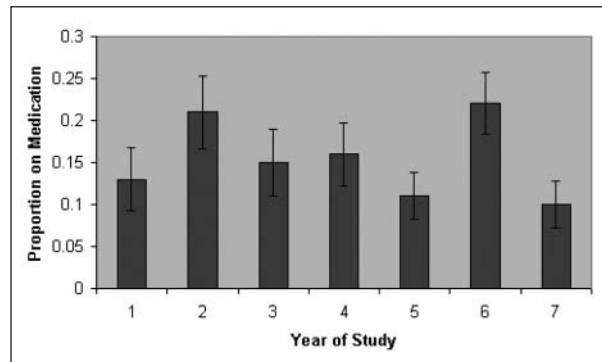


Figure 2. Standard Deviation for the Proportion of Children Taking Medication Calculated for Each Year of Study
X-axis: 1= 2001, 2= 2002
Note: The confidence lines represent one standard deviation

To assess the nature of the trend in the proportion of patients on psychotropic medications, a simple Pearson correlation was calculated between the proportion of patients receiving these medications in a particular year and the number of years from the beginning of study (across years 1 to 70). This yielded a negative correlation of $r = -.22$, which was not statistically significant ($P = .63$) and demonstrated a small trend of a decreasing proportion of children receiving these medications across the 7 years examined in this sample.

Discussion

In this study, there was an increase in the number of referrals mirrored by an increase in the number of children diagnosed with behavior problems. The overall percentage of children on medications at time of first visit, although displaying some variability, did not show a statistically significant increase over the 7-year period from 2001 to 2007. It is important to point out that we examined psychotropic medication use trends between 2001 and 2007, whereas most of the studies currently available for review analyzed trends prior to this time. The results of this study do not appear to show the same pattern of increased medication usage that has been documented in other more recent studies. This may be because of regional differences or because of the fact that Iowa is largely a rural state. A third reason may be the fact that most of the other studies already published have evaluated prescribing trends in children in general, whereas we chose to focus solely on children diagnosed with behavior disorders.

Previous studies have reported greatly increased number of referrals and a significant increase in the number of children taking psychotropic medications over the previous decade in Great Britain and the United States.¹⁻⁴ Rani

et al³ in the United Kingdom noted the overall prevalence of antipsychotic usage almost doubling within a 13-year study period from 1992 to 2005.³ The study by Zito et al⁴ evaluated findings via US geographic region, including cohorts of patients enrolled from Medicaid programs located in a Midwestern state and a mid-Atlantic state, in addition to patients from an health management organization setting in the Northwest. In all 3 data sources, the frequency of psychotropic medication prescription increased dramatically from 1991 to 1995.⁴

Some studies have specifically evaluated the usage of antipsychotic medication in children. Patel et al² evaluated 3 state Medicaid programs in the Midwestern, Southern, and Western United States. They found that, from 1996 to 2001, the prevalence of total antipsychotic medication usage increased in every program and, in particular, the use of atypical antipsychotics dramatically increased.² Cooper et al¹ found that the proportion of uninsured (TennCare) children who became new users of antipsychotic medications nearly doubled from 1996 to 2001.

Despite recent studies documenting widespread increasing use of psychotropic medications in children, this may not be the universal case. A study by DeBar et al⁵ in Oregon showed that of 743 preschoolers identified as having behavioral or emotional problems, 16% received psychotropic medication, and on average children received this medication about 6 months after the initial identification of their behavioral diagnosis. This would indicate that many clinicians try alternative approaches in these children before resorting to pharmacotherapy. In this study, we observed no statistically significant increase in the proportion of children on medication from the population of children with diagnoses of behavioral problems.

No pharmacotherapy is currently approved for use in the pediatric population with disruptive behavior and related disorders. A recent review by Findling⁶ suggested that atypical antipsychotic treatment might be useful in patients who present with very aggressive behavior. In 2007, the US Food and Drug Administration (FDA) approved one atypical antipsychotic, risperidone, for 2 types of treatment in the pediatric population: (a) for treatment of schizophrenia in children aged 13 to 17 years and (b) for treatment of bipolar I disorder in children aged 10 to 17 years.⁷ However, limited research is available on either the prescription patterns or effectiveness of atypical antipsychotic medications in young pediatric patients displaying challenging behaviors. Limited data are available on potential side effects of antipsychotic medications in the pediatric population. A recent multistudy review by Roke et al⁸ of side effects of antipsychotic medications in children and adolescents found that some antipsychotics elevated serum prolactin levels; there is a possibility of

persistent prolactin elevation for up to 2 years in children treated with risperidone. Prolactin-related side effects, such as gynecomastia, galactorrhea, irregular menses, and sexual dysfunction, were reported by 4.8% of the children and adolescents in that study.⁸ Other studies have documented an increased incidence of dizziness/orthostasis, QTc prolongation, myocarditis, sedation/somnolence, liver toxicity, neutropenia, and agranulocytosis in children and adolescents taking antipsychotic medications.⁹ The most common concerns associated with pediatric use of antipsychotic medication are weight gain and metabolic sequelae. A recent study of the cardiometabolic risk of second-generation antipsychotic medications in children and adolescents found that first-time users had significant weight gain (an average of 4.4 to 8.5 kg over a 10-12-week period) and varied metabolic changes with each of the 4 antipsychotic medications studied.¹⁰ The American Diabetes Association (ADA) consensus statement from 2004 acknowledges that such changes in body weight are concordant with changes in serum lipids. The consensus statement reported that, of the most commonly used atypical antipsychotics, clozapine and olanzapine produced the greatest weight gain and were associated with the greatest increases in total cholesterol, low-density lipoprotein cholesterol, and triglycerides and with decreased high-density lipoprotein cholesterol. The ADA reported that risperidone and quetiapine were associated with intermediate effects on serum lipids.¹¹ Clearly, caution should be exercised when prescribing these medications.

Of published studies addressing the incidence, indications, effectiveness, and safety of the use of psychotropic medications in children with behavior problems, many of the previously studied subjects also carried diagnoses of autism spectrum disorder^{12,13} or displayed cognitive disability.^{14,15} In this study, we sought to exclude children with any degree of autism spectrum disorder or intellectual disability from the study population, based on the presumption that children in these groups would possibly be more likely to have a higher incidence of psychotropic medication usage and consequently skew the data. As our results reflect patterns of psychotropic medication usage only in typically developing children, these results are distinct from much of the previously published data.

Conclusion

There is currently much debate in the scientific literature and in the media on the use of psychotropic medications in children and adolescents in general. We do not yet have well-established data regarding either the long-term consequences of treatment (medicated or not) or the

long-term consequences of lack of treatment. The results of this study suggest that the previously documented upward trend of psychotropic medication usage in pediatric patients may not be applicable to all diagnostic categories and/or all areas of the United States.

Among our study limitations was the small sample size of 709 patients. It is difficult to compare our results with those of the much larger similar studies. However, our study design is unique in sampling a specific population rather than the entire population at large. Our results suggest that the dramatic increases in psychotropic medication usage documented in other studies may be related to diagnoses other than behavior disorders or possibly geographic influences.

This study is limited in its reflection of prescribing practices in a specific part of the country and reflects the psychotropic prescription practices within a specific referral network. As such, it is difficult to know if the study findings can be generalized to other parts of the country. More studies are needed to determine if psychotropic medication prescription practices vary across diagnostic categories in other parts of the country and/or the world as well. More research is needed further to document trends in prescription patterns, including diagnostic categories of children. More studies are warranted using the same and other databases. A meta analysis of multiple studies monitored periodically across time could be most useful in understanding trends in patient population characteristics and/or physician practices and standards of care.

As this study looked at medication usage at time of referral, these findings are not a reflection of the practice of this clinic as much as the practice in the regional community. We can conclude from these results that in this particular clinic in this rural state, we have not seen significant increases in the percentage of psychotropic medication usage in young children of typical development who display challenging behavior.

Many researchers of prevalence patterns agree that the use of psychotropic medications in young children with behavior disorders needs to be further studied from a medical, legal, and regional perspective. Overall, the current consensus is that to ensure the safety and well-being of children, much more prevalence research is needed. Such studies could be valuable in developing greater understanding of the nature of current psychotropic medication prescription practices and standards of care in relation to regional, diagnostic, and other compelling variables.

Authors' Note

Dr Seyfer is now with the Division of Behavioral Health, The Ohio State University, Nationwide Children's Hospital, Columbus, OH.

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Declaration of Conflicting Interests

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